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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,013	12/23/2005	Francesco Makovec	Q91867	2981

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EXAMINER	
CHO, JENNIFER Y	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,013	MAKOVEC ET AL.	
	Examiner	Art Unit	
	JENNIFER Y. CHO	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/08 has been entered.

Claims 1-2, 4-15 are pending in this application. Claim 15 has been newly added.

Response to Arguments

Applicant's arguments are moot in view of the new grounds of rejection.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makovec et al. (US 5,130,474), in view of Midler et al. (US 5,314,506), further in view of Green (US 7,122,083).

The claims are drawn to a method for the preparation of crystalline dexloxiglumide by crystallization of the crude product from solvent, characterized in that isopropyl ether is used as the solvent. Applicants' have also embodied a method of crystallization by adding a seeding of microcrystalline dexloxiglumide to a supersaturated solution of crude dexloxiglumide, wherein the dexloxiglumide is in crystalline particle form having a percentage by volume of less than 15% of fine particles having dimensions less than 10 μm, and an average particle size value of between 10 and 130 μm.

Makovec et al teaches the preparation of crystalline dexloxiglumide and related compounds with antagonistic activity towards cholecystokin (table 3, compound 11). Makovec also teaches the crystallization of products in the presence of isopropyl ether (table 3, compounds 8 and 9).

Makovec et al. is deficient in that it is silent about the use of isopropyl ether in the crystallization of dexloxiglumide. Makovec also does not teach the crystallization step, by adding a seeding of microcrystalline dexloxiglumide to a supersaturated solution.

Midler, Jr. et al teaches a crystallization method to improve crystal structure and size with the help of seeding a supersaturated solution (col 1, lines 50-60).

Green teaches a system for making crystals by controlled crystal nucleation and growth zones by preferentially forming crystals of a desired category for pharmaceutical

applications (abstract). This is done by seeding to control crystal nucleation (column 1, lines 61-65) by growing the crystals to a desired size (column 3, lines 62-63; column 4, lines 31-33, 45-50). Green exemplifies crystals grown between 80 and 380 μm (column 15, lines 52-53).

With regard to the percentage, dimensions and size of dexloxiglumide, it is the position of the Examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the percentage, dimensions and size of dexloxiglumide. The Applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by Applicant, the preparation of crystalline dexloxiglumide.

Therefore, it would have been prima facie obvious to use isopropyl ether as the solvent to recover the dexloxiglumide during the crystallization process as disclosed by Makovec because a skilled artisan would be motivated to choose alternative solvents as a matter of choice depending on such factors as availability and cost. It would have also been obvious to one having ordinary skill in the art to have used the crystallization technique as disclosed by Midler Jr and Green during the process of crystallization to improve the crystal structure and size of dexloxiglumide with a reasonable expectation of success. Also a skilled artisan would purify the product obtained from the teaching of Makovec, as it is advantageous to use a pure product for further biological/clinical studies. Accordingly, one of ordinary skill in the art would be motivated to prepare the

instant products and compositions with anti-cholecystokinin activity with high purity by modifying the process parameters, using routine practices of crystallization.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571) 272 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

/SHAILENDRA - KUMAR/
Primary Examiner, Art Unit 1621